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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/247,886 | 02/10/1999 | JUHA PUNNONEN | 18097-030200 | 8163 |

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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/247,886

Applicant(s)

PUNNONEN ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 51-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-13, 17-23 and 51-64 is/are allowed.
- 6) ☒ Claim(s) 1, 14-16 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicants' amendments filed 8-20-01 and 1-22-02 have been entered. Claims 2, 3, 14, 16-18, 51, 53, 57-59, 61 and 62 have been amended. Claims 65-67 have been added. Claims 1-23 and 51-67 are pending and under consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1 and 14-16 remain rejected and claims 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemmer et al. 1997 (AG) in view of Ledley et al., 1994 (AH) and

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Patten et al., 1997 (BG) and is repeated for the reasons of record. Applicant's arguments filed 1-22-02 have been fully considered but they are not persuasive.

Claims 65-67 are newly added claims and are directed to a recombinant cell-specific binding moiety comprising a DNA binding domain and a cell-specific ligand having an enhanced ability to bind to a target cell, and a composition comprising said recombinant cell-specific binding moiety for eliciting an immune response.

Applicants argue that Ledley and Patten do not teach creating a library of recombinant polynucleotides by recombining two different nucleic acids encoding different polypeptide domains having different functions. Applicants further argue that Patten does not teach or suggest using DNA shuffling to produce cell-specific binding molecules with abilities to increase uptake or specificity of a genetic vaccine and no suggestion in the cited references to combine the teachings to arrive at the claimed invention (amendment, p. 12-13). This is not found persuasive because of the reasons of record. Stemmer teaches a method of repeated cycles of mutagenesis, DNA shuffling and selection to screen for polynucleotides conferring a **desired phenotype** and/or encoding a protein having an **advantageous predetermined property**. Ledley teaches production of a chimeric recombinant DNA-binding protein comprising a first element for binding to a receptor on a target cell and a second element required for binding to DNA, such as histone or transacting regulatory element, for **effecting or enhancing gene transfer** into the target cells. It would have been obvious for one of ordinary skill at the time of the invention that the ability of **effecting or enhancing gene transfer** as taught by Ledley would be the **desired**

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phenotype or advantageous predetermined property as taught by Stemmer. In addition, Patten teaches “viral vaccine vectors can be enhanced by DNA shuffling to give desired properties of tropism, stability and expression level”, and DNA shuffling could be a tool “ for increasing the efficiency and success rate of the development of novel whole organism, viral, bacterial and recombinant protein vaccines”. Thus, according to the collective teachings of Stemmer, Ledley and Patten, it would have been obvious for one of ordinary skill in the art at the time of the invention to produce and screen for a recombinant molecule that encodes a binding molecule that can bind to a nucleic acid and to a cell-specific receptor as taught by Ledley via the DNA shuffling method as taught by Stemmer and said recombinant molecule has an ability to increase uptake or specificity of a genetic vaccine for a target cell as taught by Stemmer, Ledley and Patten.

Applicants argue that the cell-specific binding ligand of the binding moiety in claims 14, 15 and 65-67 has enhanced target cell binding and Ledley does not teach or suggest any modification of the ligand binding element for any purpose (amendment, page 14). This is not found persuasive because of the reasons of record and the reasons set forth above. Since the collective teachings of Stemmer, Ledley and Patten would motivate one of ordinary skill to produce a recombinant molecule that encodes a binding molecule that can bind to a nucleic acid and to a cell-specific receptor via DNA shuffling and said recombinant molecule has enhanced gene transfer efficiency or advantageous predetermined property, therefore, the produced recombinant molecule would have an enhanced ability to bind to a target cell.

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Conclusion

Claims 1, 14-16 and 65-67 are rejected. Claims 2-13, 17-23 and 51-64 are in condition for allowance.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

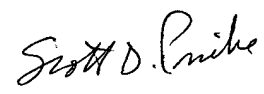
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER